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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
RAO, MANJUNATH N	

ART UNIT	PAPER NUMBER
1652	7

DATE MAILED: 10/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/816,825	BISTRUP ET AL.	
	Examiner	Art Unit	
	Manjunath N. Rao, Ph.D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-87* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-87* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 30-87 are pending and now under consideration in this application.

Applicants' amendments and arguments filed on 7-29-03, paper No.5, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 31, and claims 32 to 36, 69-72 which depend from claim 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 31 recites the phrase "encodes a functional domain of glycosylsulfotransferase-3". The metes and bounds of the above phrase is not clear to the Examiner. It is not clear to the Examiner as to whether "encodes a functional domain" means that the encoded peptide catalyzes the transfer of a sulfate group from a donor compound. As applicants have not made this clear, Examiner has concluded that said encoded peptide has not catalytic function.

Claim 60 and claims 61, 63, 65-68 which depend from claim 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 60 recites the

phrase "comprises a functional domain of glycosylsulfotransferase-3". The metes and bounds of the above phrase is not clear to the Examiner. It is not clear to the Examiner as to whether "functional domain" means that the encoded peptide catalyzes the transfer of a sulfate group from a donor compound. As applicants have not made this clear, Examiner has concluded that said encoded peptide has not catalytic function.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 60-61, 63, 65, 69, 71-72, 30-37, 39-56, 73-75, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DNA with SEQ ID NO:1 encoding a full length polypeptide with SEQ ID NO:2 having glycosylsulfotransferase activity, does not reasonably provide enablement for any such DNA that hybridizes to SEQ ID NO:1 under stringent conditions, wherein said polynucleotide encodes a *functional domain* of GST-3 or any polynucleotide comprising a fragment of at least 25 nucleotides of a nucleotide sequence having at least 90% nucleotide sequence identity to SEQ ID NO:1, or any polynucleotide comprising a nucleotide sequence which encodes a fragment of at least about 15 contiguous amino acid sequence of SEQ ID NO:2 comprising a sulfate acceptor/donor binding region of glycosylsulfotransferase-3 or any polynucleotide comprising a nucleotide sequence which encodes a fragment of at least 15 amino acids of SEQ ID NO:2 wherein the fragment comprises a *functional domain* of a glycosylsulfotransferase-3, or encodes a fragment of at least 15 amino

acids of a polypeptide having at least about 60% amino acid sequence identity to SEQ ID NO:2 wherein said fragment comprises a sulfate donor binding or sulfate acceptor binding site, vectors and host cells comprising such polynucleotides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 60-61, 63, 65, 69, 71-72, 30-37, 39-56, 73-75 are so broad as to encompass any DNA which are fragments of SEQ ID NO:1 including variants mutants and recombinant fragments, and vectors and host cells comprising such DNAs and method of making the fragments of peptides encoded by said DNA. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of DNA sequences that are broadly encompassed by the claims.

The applicants propose to use the above polynucleotides for a variety of processes such as recombinant protein preparation (whose use is not known), as hybridization probes, and research applications, diagnostic applications, therapeutic agent screening/discovery/preparation applications as well as therapeutic compositions (see pages 12-30). The nucleotide sequence

determines the type of protein and the ultimate function of the encoded protein and only nucleic acids which encode a polypeptide with a specific activity can be envisioned as having any use.

Furthermore, since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide sequence with SEQ ID NO:1 and encoded amino acid sequence of only a single glycosyl sulfotransferase-3, SEQ ID NO:2. It would require undue experimentation of the skilled artisan to make and use the claimed polynucleotides that hybridizes to SEQ ID NO:1 under stringent conditions, wherein said polynucleotide encodes a *functional domain* of GST-3 or any polynucleotide comprising a fragment of at least 25 nucleotides of a nucleotide sequence having at least 90% nucleotide sequence identity to SEQ ID NO:1, or any polynucleotide comprising a nucleotide sequence which encodes a fragment of at least about 15 contiguous amino acid sequence of SEQ ID NO:2 comprising a sulfate acceptor/donor binding region of glycosylsulfotransferase-3 or any polynucleotide comprising a nucleotide sequence which encodes a fragment of at least 15 amino acids of SEQ ID NO:2 wherein the fragment comprises a *functional domain* of a glycosylsulfotransferase-3, or encodes a fragment of at least 15 amino acids of a polypeptide having at least about 60% amino acid sequence identity to SEQ ID NO:2 wherein said fragment comprises a sulfate donor binding or sulfate acceptor binding site, vectors and host cells comprising such polynucleotides. The specification is limited to teaching the use

of SEQ ID NO: 1 as encoding a polypeptide with SEQ ID NO:2 as a glycosylsulfotransferase but provides no guidance with regard to making variant polynucleotides that hybridize to SEQ ID NO:1 under stringent conditions, wherein said polynucleotide encodes a *functional domain* of GST-3 or any polynucleotide comprising a fragment of at least 25 nucleotides of a nucleotide sequence having at least 90% nucleotide sequence identity to SEQ ID NO:1, or any polynucleotide comprising a nucleotide sequence which encodes a fragment of at least about 15 contiguous amino acid sequence of SEQ ID NO:2 comprising a sulfate acceptor/donor binding region of glycosylsulfotransferase-3 or any polynucleotide comprising a nucleotide sequence which encodes a fragment of at least 15 amino acids of SEQ ID NO:2 wherein the fragment comprises a *functional domain* of a glycosylsulfotransferase-3, or encodes a fragment of at least 15 amino acids of a polypeptide having at least about 60% amino acid sequence identity to SEQ ID NO:2 wherein said fragment comprises a sulfate donor binding or sulfate acceptor binding site, vectors and host cells comprising such polynucleotides and also methods to use such polynucleotides or with regard to other uses. In view of the great breadth of the claim, amount of experimentation required to make the claimed polynucleotides, the lack of guidance, working examples, and unpredictability of the art in predicting function from a polypeptide primary structure (e.g., see Ngo et al. in The Protein Folding Problem and Tertiary Structure Prediction, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495, Ref: U, Form-892), the claimed invention would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to use the full scope of the polypeptides encompassed by this claim.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims,

and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any polynucleotide that hybridizes to SEQ ID NO:1 under stringent conditions, wherein said polynucleotide encodes a *functional domain* of GST-3 or any polynucleotide comprising a fragment of at least 25 nucleotides of a nucleotide sequence having at least 90% nucleotide sequence identity to SEQ ID NO:1, or any polynucleotide comprising a nucleotide sequence which encodes a fragment of at least about 15 contiguous amino acid sequence of SEQ ID NO:2 comprising a sulfate acceptor/donor binding region of glycosylsulfotransferase-3 or any polynucleotide comprising a nucleotide sequence which encodes a fragment of at least 15 amino acids of SEQ ID NO:2 wherein the fragment comprises a *functional domain* of a glycosylsulfotransferase-3, or encodes a fragment of at least 15 amino acids of a polypeptide having at least about 60% amino acid sequence identity to SEQ ID NO:2 wherein said fragment comprises a sulfate donor binding or sulfate acceptor binding site, vectors and host cells comprising such polynucleotides because the specification does not establish: (A) regions of the protein glycosylsulfotransferase-3 structure which may be modified without affecting its catalytic activity; (B) the general tolerance of glycosylsulfotransferase-3 to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residues of any glycosylsulfotransferase-3 with an expectation of obtaining the

desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any DNA fragment of SEQ ID NO:1 including those hybridizing to SEQ ID NO:1. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of the claimed DNAs and determination of their use is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

In response to the previous Office action, applicants have traversed the above rejection exhaustively arguing in summary that the specification enables the claimed invention. In view of applicants arguments traversing the rejection under 35 U.S.C. 112, Ist as non-enabled due to lack of utility, Examiner has withdrawn that rejection. However, the above rejection is maintained. Applicants reiterate their argument that the specification teaches as to how to make the claimed nucleic acid and how to use the claimed nucleic acids. Applicants submit that the specification discusses various uses including use as probes primers to identify GST-3 and in diagnostic applications and to prepare GST-3 polypeptides using standard techniques. While reiterating what is claimed by them, applicants argue that court allows for considerable experimentation and that even then the only experimentation needed is to determine whether a given fragment (of what ?) catalyzes transfer of a sulfate group from a sulfate donor to sulfate acceptor, comprises GST-3 acceptor binding and donor binding site, all of which are explained in the specification

and involve routine techniques. Examiner respectfully disagrees with such an argument as being persuasive to overcome the above rejection. First a of all applicants are claiming polynucleotides and not polypeptides. Furthermore, while applicants may have taught assays for determining the sulfate transfer activity, what they have not taught is to first of all make polynucleotides which are 75%-95% identical to SEQ ID NO:1, i.e., where exactly those skilled in the art should make changes in the nucleotide sequence such that they are 75% identical to SEQ ID NO:1 but yet maintain all functional aspects. Applicants have also not taught as to how those skilled in the art would make polynucleotide encoding a polypeptide that is 60% identical to SEQ ID NO:2, again which specific amino acid residues can be changed without affecting the activity of the polypeptide. While the specification provides generalized guidelines, it very much lacks specific guidance regarding making changes to SEQ ID NO:1 or 2. Applicants argue that they have provided working examples of the use of polynucleotide fragments. Again all these are highly generalized and lack specifics especially with respect to SEQ ID NO:1 and 2.

Applicants also argue that the relevant skill of those in the art is generally that of a doctoral level and such artisans are required to keep abreast of latest technology and as such skill of those is high. Applicants also argue that not every species in the genus need to be tested for the genus to be enabled. Examiner respectfully disagrees with such a conclusion by the applicants. While those skilled may be of doctoral level and while methods to produce variants of a known sequence, such as site-specific mutagenesis, random mutagenesis, etc. are well known to the skilled artisan, producing variants as claimed by applicants of a polynucleotide that is 2032 nucleotides in length requires that one of ordinary skill in the art be provided with guidance for the selection of which of the infinite number of variants have the claimed property.

Without such guidance one of ordinary skill would be reduced to the necessity of producing and testing all of the virtually infinite possibilities. This would clearly constitute undue experimentation. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. Such guidance has not been provided in the instant specification. Hence the above rejection is maintained.

Claims 31-36, 51-54, 60-61, 63, 69, 73-74 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of DNA molecules which are fragments of SEQ ID NO:1 encoding fragment of SEQ ID NO:2 or those which hybridize to SEQ ID NO:1 under stringent conditions.

The specification does not contain any disclosure of the function of all DNA sequences encompassed by the claims or the amino acid sequences encoded by said DNA sequences. The genus of DNAs that comprise these above DNA molecules is a large variable genus with the potentiality of having different functions. Therefore, many functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed

genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

In view of applicants amendments to claims 45-50 Examiner has withdrawn the rejection of above claims under 35 U.S.C. 103(a) as being unpatentable over Aparicio et al. (PIR Database, Accession NoT30228, and Gene, Vol. 169:9-16, 1996) in view of Sambrook et al. (Molecular Cloning, A Laboratory Manual, 2nd Ed, ColdSpring Harbor Laboratory Press, 1989).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 30-87 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,265,192. An

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim, because the examined claim is either anticipated by, or would have been obvious over the reference claim. See, e.g., *In re Berg*, 140 F.3d 1428,46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi* 759 F.2d 887,225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 30-87 of the instant application and claims 1-6 of the reference patent are both directed to polynucleotides with SEQ ID NO:1 including variants mutants, recombinants and fragments of the same. A good number of different fragments of DNA claimed in the instant application and in the DNA in the reference patent are identical to one another. The portion of the specification (and the claims) in the reference patent that supports the recited polynucleotide includes several embodiments that would anticipate the fragments (i.e., fragments encoding peptides with or without any activity) claimed in claims 30-87 herein. Claims of the instant application listed above cannot be considered patentably distinct over claims 1-6 of the reference patent when there is specifically recited embodiment that would anticipate mainly claims 30-56 of the instant application. Alternatively, claims 30-87 cannot be considered patentably distinct over claims 1-6 of the reference patent when there is specifically disclosed embodiment in the reference patent that supports claims 1-6 of that patent and falls within the scope of claims 30-87 herein because it would have been obvious to one having ordinary skill in the art to modify claims 1-6 of the reference by selecting a specifically disclosed embodiment that supports those claims. One of ordinary skill in the art would have

been motivated to do this because that embodiment is disclosed as being a preferred embodiment within claims 1-6 of the reference patent.

In their response to the previous Office action, applicants request withdrawal of the above rejection as they have enclosed a Terminal Disclaimer disclaiming patent term beyond the expiration date of US patent No. 6,265,192. However, no such T.D. was found enclosed. Therefore in view of the absence of a T.D. Examiner continues to maintain the above rejection for reasons of record.

Claims 30-87 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-10 and 12 of U.S. Patent Application No. 10/007262, published as US 2002/0164748 A1. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim, because the examined claim is either anticipated by, or would have been obvious over the reference claim. See, e.g., *In re Berg*, 140 F.3d 1428,46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi* 759 F.2d 887,225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 30-87 of the instant application and claims 5-10 and 12 of the reference patent are both directed to polynucleotides with SEQ ID NO:1 including variants mutants, recombinants and fragments of the same and methods of making the encoded peptides. A good number of different fragments of DNA claimed in the instant application and the DNA in the reference publication are identical to one another. The portion of the specification (and the claims) in the reference application that

supports the recited polynucleotide includes several embodiments that would anticipate the fragments (i.e., fragments encoding peptides with or without any activity) claimed in claims 30-87 herein. Claims of the instant application listed above cannot be considered patentably distinct over claims 5-10 and 12 of the reference application when there is specifically recited embodiment that would anticipate mainly claims 30-87 of the instant application. Alternatively, claims 30-87 cannot be considered patentably distinct over claims 5-10 and 12 of the reference application when there is specifically disclosed embodiment in the reference application that supports claims 5-10 and 12 of that patent and falls within the scope of claims 30-87 herein because it would have been obvious to one having ordinary skill in the art to modify claims 5-10 and 12 of the reference application by selecting a specifically disclosed embodiment that supports those claims. One of ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within claims 5-10 and 12 of the reference application.

In their response to the previous Office action, applicants have indicated that they will submit a Terminal Disclaimer disclaiming patent term beyond the expiration date of US 2002/0164748 upon issuance of US 2002/0164748 or upon receipt of a Notice of Allowance in the instant case. However, as no T.D. has been filed by the applicants at this time Examiner continues to maintain the above rejection for reasons of record.

Conclusion

None of the claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 703-306-5681. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0196.

MANJUNATH RAO
PATENT EXAMINER

Manjunath N. Rao Ph.D.
October 10, 2003